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(54) DUAL CHAMBER PACING SYSTEM WITH OPTIMIZED ADJUSTMENT OF THE AV ESCAPE INTERVAL FOR TREATING CARDIOMYOPATHY

ZWEIKAMMER-HERZSCHRITTMACHER-SYSTEM MIT OPTIMIERTER VERSTELLUNG DER AV-VERZÖGERUNG ZUR BEHANDLUNG VON KARDIOMYOPATHIEN

SYSTEME DE STIMULATION CARDIAQUE BI-CAVITE PERMETTANT LE REGLAGE OPTIMAL DE L'INTERVALLE D'ECHAPPEMENT AURICULO-VENTRICULAIRE POUR TRAITER LA MYOCARDIOPATHIE

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(56) References cited:
EP-A- 0 597 728
EP-A- 0 600 631
EP-A- 0 607 951
WO-A-92/17240
US-A- 4 686 988
US-A- 5 247 929
US-A- 5 334 222

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Description

This invention relates to cardiac pacing systems generally and, in particular, to dual chamber cardiac pacing systems for delivering ventricular pacing pulses synchronized to atrial signals so as to benefit patients with cardiomyopathy and forms of congestive heart failure (CHF), and in particular Hypertrophic Obstructive Cardiomyopathy.

Hypertrophic Obstructive Cardiomyopathy (HOCM) is characterized by a narrowed left ventricular outflow tract (LVOT), which causes a significant increase in the left ventricular end systolic pressure. The narrowed LVOT is caused by an increased thickness of the interventricular septum which obstructs blood flow during systole, the time of cardiac ejection.

Symptomatic improvement of patients with HOCM can be obtained in some cases with the use of standard pharmacotherapy. However, drugs in use for this therapy have disadvantages which have been cited in the literature. Likewise, surgical intervention, e.g., septal myectomy or mitral valve replacement, is another optimal treatment. However, such surgical treatments carry a significant operative mortality and have not been shown to alter the natural history of the disease. See, "Permanent Pacing As Treatment For Hypertrophic Cardiomyopathy," by Kenneth M. McDonald et al., *American Journal of Cardiology*, Vol. 68, pp. 108-110, July 1991.

The value of dual chamber cardiac pacing and treatment of patients suffering from HOCM has been recognized in the literature. Modern multiple-mode, dual-chamber cardiac pacemakers are designed to maintain AV synchrony for damaged or diseased hearts that are unable to do so on their own. For example, a DDD pacemaker has electrical connections to both the atrium and the ventricle, senses electrical signals in both chambers of the patient's heart, and delivers atrial pacing stimuli in the absence of signals indicative of natural atrial activation, and ventricular pacing stimuli in the absence of signals indicative of natural ventricular activation. Such a dual chamber pacemaker maintains the AV synchrony of the heart by delivering ventricular pace pulses at a controlled AV interval following each atrial event.

Studies have indicated that patients suffering from HOCM may benefit from a specific mode of dual chamber pacing wherein a ventricular pacing pulse is delivered in timed synchrony with the sensed or paced atrial depolarization. Pacing the right ventricular apex before spontaneous atrio-ventricular conduction activates the ventricles is understood to alter the ventricular septal activation pattern. Since the right ventricle is caused to contract first, it pulls the septum toward the right ventricle thereby reducing the LVOT obstruction.

The literature uniformly acknowledges the potential advantages of synchronized A-V pacing for HOCM patients, stressing the importance of achieving ventricular capture. Causing "complete ventricular capture" is important to obtain the above-described septal movement, while selecting the longest AV delay that results in complete ventricular capture is important in order to maximize the atrial contribution to ventricular filling. See WO-A-9524944 (a document falling under Article 54(3) EPC) Method and Apparatus For Dual Chamber Cardiac Pacing, assigned to Medtronic, Inc., and the literature articles referenced therein. The delivered pacing pulse should provide "pre-excitation," i.e., depolarization of the ventricular apex before the septum. This altered pattern of septal contraction, as well as optimal left ventricular filling, is generally recognized as being important to this mode of pacemaker treatment. Further, it appears to be established that such synchronized AV pacing provides HOCM patients a longterm benefit, i.e., the benefit remains even after cessation of pacing, since such AV pacing causes a reduction in the obstruction of the LVOT which persists in sinus rhythm after cessation of pacing. However, the duration of the benefit is not certain.

The literature suggests that the AV escape interval should be set at the longest duration that maintains ventricular capture at different exercise levels. See the above-cited McDonald article. It has been suggested that the AV escape interval which allows for maximal pre-excitation of the ventricle by the pacing pulse can be selected by determining the AV escape interval that produces the widest paced QRS complex duration, as seen on a surface electrocardiogram. See "Impact of Dual Chamber Permanent Pacing in Patients With Obstructive Hypertrophic Cardiomyopathy With Symptoms Refractory to Verapamil and b-Adrenergic Blocker Therapy," by Fananapazir et al., *Circulation*, Vol. 8, No. 6, June 1992, pp. 2149-2161.

In the referenced WO-application assigned to Medtronic, Inc., the pacemaker periodically checks to determine a value of intrinsic AV conduction time (AVC) and subtracts therefrom a ventricular sense offset interval (VSO) to get the AV escape interval. After a waveform of the ventricular depolarization resulting from complete capture is noted and recorded for comparison, the AV escape interval is set to a lengthened value, resulting in one or more ventricular sense events. The value of AVC is determined as the time difference between the atrial event and the sensed R-wave. Following this, the pacemaker AV escape interval is reduced further until the pacemaker finds an R wave with a waveform that indicates good capture. The difference between AVC and the capture value of A-V is VSO, and the pacemaker thereafter sets AV = AVC - VSO .

The prior art techniques for AV synchronous pacing of HOCM patients recognize the necessity to periodically evaluate the AV delay, or AV escape interval. The patient's spontaneous atrio-ventricular conduction time generally will change with heart rate, i.e., from rest to exercise. Moreover, simultaneous drug treatment such

as beta blockers may also modify AV conduction time and require renewed evaluation of the AV delay. The importance of periodically making an accurate determination of the optimized AV interval thus takes on significance. If the AV delay is adjusted to a value which is too short, in order to ensure complete ventricular capture, the atrial contribution to ventricular filling may be compromised. However, if the AV escape interval is adjusted to too great a value, ventricular capture is compromised, and there may be episodes of no ventricular pacing or the ventricular pace may not contribute the best possible reduction of the LVOT obstruction. Accordingly, it is important in this therapy to be able to continuously or periodically adjust the AV escape interval to optimize it for HOCM therapy.

The present invention provides a dual chamber pacemaker system, having atrial sense means for sensing signals from a patient's atrium, ventricular sense means for sensing ventricular signals from a patient, ventricular pace means for generating and delivering ventricular pacing pulses to said patient's right ventricle, AV_{esc} means for setting and timing an AV escape interval from the occurrence of a sensed atrial signal, and sync control means for controlling delivery of ventricular pacing pulses at the time out of said AV escape interval in the absence of a sensed ventricular signal, characterized by FFRS, QRS or Ventricular septal pre-excitation sense means for detecting FFRSs, QRSs or ventricular septal pre-excitation following delivered ventricular pacing pulses, further comprising analyzing means for analyzing said detected FFRSs, QRSs or ventricular septal pre-excitation and determining from variations in said detected FFRSs, QRSs or ventricular septal pre-excitation an indication for adjustment of said AV escape interval, said AV_{esc} means having adjusting means for adjusting said AV escape interval in accordance with said indication.

This invention thus provides an apparatus for adjustment of the AV delay for dual chamber pacing therapy in patients with HOCM. The apparatus is based upon an improved system for determining the optimum AV escape interval, including both the means of detecting data from which the optimum interval can be derived, and the operating algorithm for finding an optimized operating value of AV delay. The terms AV delay and AV escape interval (AV_{esc}) are used interchangeably.

In a first preferred embodiment, the pacemaker of this invention locates the far field R-wave sense (FFRS) and utilize data from the FFRS signals for determining the optimum AV interval. As is known, the FFRS is a representation, or measure of the QRS, but sensed in the atrium. More specifically, one embodiment is based upon our observation that patients with HOCM and like conditions are likely to produce an FFRS which is late relative to the delivered ventricular pacing pulse. Accordingly, an embodiment of the invention is to adjust the AV interval through a series of respective values, and measure the time between each ventricular pacing pulse and the following FFRS or QRS, i.e., the VP-FFRS or VP-QRS time. The pacemaker determines the AV_{esc} corresponding to the longest VP-FFRS time, which longest time corresponds to the latest septal activation and accordingly represents an optimized value of AV escape interval. The AV_{esc} is then reset in accord with the determined optional AV value. More specifically, the pacemaker incorporates an algorithm for determining the knee of the VP-FFRS or VP-QRS curve, and sets the AV interval to a value just slightly less than the knee. Likewise, the FFRS duration, or QRS duration or "width" reaches a maximum value as the AV interval is shortened to about the longest value consistent with good capture. A second embodiment thus involves similarly adjusting the AV escape interval, e.g., scanning from a relatively high AV value resulting in natural ventricular depolarizations, toward shorter values which result in capture and evoked R-waves, and measuring corresponding values of FFRS or QRS duration. After the duration data is obtained from the scan, an algorithm analyzes the data and determines the AV_{esc} value corresponding to the breakpoint where QRS or FFRS duration reaches a high value plateau.

The invention can be practiced either by adjusting AV escape interval when the patient presents for programming, or when the patient is ambulatory. In the case of a patient whose pacemaker is in communication with a programmer, the algorithm-driving data may be obtained from the ECG as recorded from skin electrodes which are connected to the programmer; from sub-Q electrodes as used in a syncope monitor; or from the far field electrogram as recorded from the atrial channel of the pacemaker and communicated to the programmer. The programmer collects and displays the appropriate data so that the physician can inspect it and pick the desired AV setting or, alternatively, the pacemaker system can automatically select the optimum setting and present it to the physician as a recommended value. In the case of an implanted pacemaker, the pacemaker can continuously or periodically, e.g., once a day or more frequently, determine a new adjusted AV escape interval and override the previously programmed value.

Preferred embodiments will now be described by way of example only, with reference to the accompanying drawings.

Figure 1 is a perspective representation of a pacemaker system according to this invention showing an implantable pacemaker connected to a patient's heart.

Figure 2 is a block diagram of a pacemaker system according to this invention, showing a pacemaker interconnected with an external programmer and with ECG leads.

Figure 3 is a block diagram of the primary functional components of a pacemaker used in the system of this invention.

Figure 4A is a generalized flow diagram illustrating

steps taken in synchronous pacing in accordance with this invention, including adjusting AV escape interval for optimizing HOCM therapy; Figure 4B is a flow diagram illustrating the primary steps of a pacemaker routine which includes searching to determine a HOCM-optimized AV escape interval.

Figure 5A is a representative data plot of QRS or FFRS duration as a function of pacemaker AV escape interval; Figure 5B is a representative plot of VP-FFRS or VP-QRS time interval as a function of pacemaker escape interval.

Figure 6A is a flow diagram illustrating steps taken by the pacemaker system of this invention in acquiring data for a determination of AV interval adjustment; Figure 6B is a flow diagram of a routine for determining optimized AV escape interval from data representative of FFRS or QRS duration; Figure 6C is a flow diagram of a routine for determining optimized AV escape interval from data representative of the time interval between ventricular pace pulses and evoked QRS or FFRS signals.

Figure 1 illustrates the external configuration of a dual chamber pacemaker 6, which is provided with a hermetically sealed enclosure 8, typically fabricated of biocompatible metal such as titanium. Mounted to the top of the enclosure 8 is a connector block assembly 12, which receives electrical connectors located on the proximal ends of leads 14 and 16. Lead 16 is an atrial pacing lead, carrying two electrodes 20 and 21. Electrodes 20 and 21 are used both to sense atrial depolarizations and to deliver atrial pacing pulses. Atrial pacing pulses may be delivered between electrode 20 and electrode 21 or between electrode 21 and the housing 8 of the pacemaker 6. Sensing of atrial depolarizations may occur between electrode 20 and electrode 21 or between either of electrode 20 and 21 and the housing 8 of the pacemaker 6. Also, alternatively, FFRS signals may be detected by electrodes placed at other positions, e.g., at locations 24, 25.

Similarly, lead 14 represents a ventricular bipolar pacing lead, carrying two electrodes 28 and 29. As discussed above in conjunction with atrial lead 16, electrodes 28 and 29 are used to sense and pace the ventricle. Ventricular pacing may be accomplished between electrodes 29 and 28 or between electrode 29 and the conductive housing 8 of pacemaker 6. Sensing of ventricular signals, including depolarizations (QRS-waves) and repolarizations (T-waves) may be accomplished between electrodes 29 and 28 or between either of electrodes 29 and 28 and the housing 8 of the pacemaker 6.

As discussed in the present application, the preferred embodiments of the pacemaker 6 operate in a DDD or DDDR pacing mode, wherein pacing pulses are delivered to both atrium and ventricle and wherein atrial and ventricular depolarizations are both effective to inhibit delivery of the next scheduled pacing pulse in the chamber in which they are detected. While the present invention is believed optimally practiced in a pacemaker operating in DDD pacing mode, in some patients there may also be a benefit to operating the device in VDD or DVI mode, which provides ventricular pacing pulses synchronized only to sensed atrial depolarizations or only delivered to atrial pacing pulses, respectively, depending upon the specific underlying heart condition of the patient. However, DDD mode is expected to be the mode most widely used to practice the present invention.

Figure 2 illustrates the pacemaker 6 in block diagram form, coupled to a human heart 10, in conjunction with an external programmer/display apparatus corresponding to those typically employed to program modern, multi-programmable implantable pacemakers. Within the housing of the pacemaker are located the pacing circuitry 320, which includes circuitry performing all of the basic timing, stimulation and sensing functions of a cardiac pacemaker and a microprocessor circuit 302, which controls the timing intervals provided by the pacing circuitry 320. Pacing circuitry 320 also includes a bidirectional telemetry circuit coupled to an antenna 334, allowing transmission of information from external programmer 4 into the pacemaker 6 to modify its parameters and allowing transmission of information from the pacemaker 6 to the external programmer 4, again generally corresponding to telemetry and programming systems presently existing in commercially marketed multi-programmable implantable pacemakers.

The programmer 4 also includes a corresponding antenna 100 coupled to a telemetry/antenna driver circuit 102 which serves to demodulate telemetry signals received from antenna 334 of the pacemaker, and to apply them in parallel or serial digital format to input output (I/O) unit 108, where they in turn may be applied to a video monitor 112 via graphic interface 110, and/or provided to central processing unit 114 and/or printer 118. Microprocessor 114 controls the operation of the programmer/display apparatus, and is responsive to physician entered commands via keyboard 116, for controlling programming signals sent to the pacemaker, as well as for controlling operation of the video display 112 and printer 118. Also illustrated is an ECG interface 104, coupled to three ECG electrodes 106 which can be placed upon the patient's body. ECG interface 104 provides sensed electrograms to input/output device 108, where they in turn may be provided to the video display 112, the central processing unit 114 or the printer 118. The ECG capability is used for treatment according to this invention for a patient who is available for initial or subsequent programming.

Figure 3 is a block functional diagram of the pacemaker illustrated in Figure 1, as connected to a human heart 10. The circuitry illustrated is all located within the conductive housing or can 8 of the pacemaker, as illustrated in Figure 1, and the bipolar leads 14 and 16 are illustrated schematically as coupled directly to the circuit. However, of course, in the actual device they would

be coupled by means of removable electrical connectors inserted in the connector block 12, as illustrated in Figure 1.

The pacemaker is divided generally into a microcomputer circuit 302 and a pacing circuit 320. A pulse generator circuit 340 includes a ventricular pulse generator circuit coupled to the heart 10 by means of electrodes 29 and 28 on lead 14, as well as an atrial pulse generator circuit coupled to the heart 10 by means of atrial electrodes 20 and 21, located on lead 16. Similarly, pacing circuit 320 includes atrial and ventricular sense amplifiers in sense amplifier circuit 360, coupled to the atrium and ventricle by means of leads 14 and 16 as well. The ventricular sense amplifier provides for separate detection and identification of QRS-wave signals, in a known manner; it may also provide for detection and identification of T-wave signals. The atrial sense amplifier provides for respective identification of P-waves and FFRS signals. The output circuit 340 and sense amplifier circuit 360 may contain pulse generators and sense amplifiers corresponding to any of those presently employed in commercially marketed cardiac pacemakers. Control of timing and other functions within the pacemaker circuit is provided by digital controller/timer circuit 300, which includes a set of timers and associated logic. Digital controller/timer circuit 330 defines the basic pacing interval of the device, which may take the form of an A-A escape interval initiated on atrial sensing or pacing and triggering atrial pacing at the expiration thereof, or may take the form of a V-V escape interval, initiated on ventricular sensing or pacing and triggering ventricular pulse pacing at the expiration thereof. Digital controller/timer circuit 330 similarly defines the A-V escape interval, AV_{esc}, discussed in detail below. The specific values of the intervals defined are controlled by the microcomputer circuit 302 by means of data and control bus 306. Sensed atrial depolarizations and FFRSs are communicated to the digital controller/timer circuit 330 on A event line 352; and ventricular depolarizations (QRS-waves) are communicated to the digital controller/timer circuit 330 on V event line 354. In order to trigger generation of a ventricular pacing pulse, digital controller/timer circuit 330 generates a trigger signal on V trig line 342. Similarly, in order to trigger an atrial pacing pulse, digital controller/timer circuit 330 generates a trigger pulse on a trig line 344.

Digital controller/timer circuit 330 also defines time intervals for controlling operation of the sense amplifiers in sense amplifier circuit 360. Typically, digital controller/timer circuit 330 will define an atrial blanking interval following delivery of an atrial pacing pulse, during which atrial sensing is disabled, as well as ventricular blanking intervals following atrial and ventricular pacing pulse delivery, during which ventricular sensing is disabled. Digital controller/timer circuit 330 will also define an atrial refractory period during which atrial sensing is disabled, this refractory period extending from the beginning of the A-V escape interval following either a sensed or paced atrial depolarization, and extending until a predetermined time following sensing of a ventricular depolarization or delivery of a ventricular pacing pulse. Digital controller/timer circuit 330 similarly defines a ventricular refractory period following ventricular sensing or delivery of a ventricular pacing pulse, which is typically shorter than the portion of the atrial refractory period following ventricular sensing or pacing. Digital controller/timer circuit 330 also controls sensitivity settings of the sense amplifiers 360 by means of sensitivity control 350. In the embodiment illustrated in Figure 3, the pacemaker is provided with a piezo electric sensor 316 which is intended to monitor patient activity, in order to allow provision of rate responsive pacing, such that the defined pacing rate (A-A escape interval or V-V escape interval) increases with increased demand for oxygenated blood. Sensor 316 generates electrical signals in response to sensed physical activity which are processed by activity circuit 322 and provided to digital controller/timer circuit 330. Activity circuit 332 and associated sensor 316 may correspond to the circuitry disclosed in U.S. Patent No. 5,052,388, issued to Betzold et al., and U.S. Patent No. 4,428,378, cited here to show what is known and may be used for this invention. Similarly, the present invention may be practiced in conjunction with alternative types of sensors such as oxygenation sensors, pressure sensors, pH sensors and respiration sensors, all well known for use in providing rate responsive pacing capabilities. Alternatively, QT time may be used as the rate indicating parameter, in which case no extra sensor is required. Similarly, the present invention may also be practiced in non-rate responsive pacemakers.

Transmission to and from the external programmer 4 illustrated in Figure 2 is accomplished by means of antenna 334 and associated RF transmitter and receiver 322, which serves both to demodulate received downlink telemetry and to transmit uplink telemetry. Crystal oscillator circuit 338 provides the basic timing clock for the circuit, while battery 318 provides power. Power on reset circuit 336 responds to initial connection of the circuit to the battery for defining an initial operating condition and similarly, resets the operative state of the device in response to detection of a low battery condition. Reference mode circuit 326 generates stable voltage reference and currents for the analog circuits within the pacing circuit 320, while analog to digital converter ADC and multiplexor circuit 328 digitizes analog signals and voltage to provide real time telemetry of cardiac signals from sense amplifiers 360, for uplink transmission via RF transmitter and receiver circuit 332. Voltage reference and bias circuit 326, ADC and multiplexor 328, power on reset circuit 336 and crystal oscillator circuit 338 may correspond to any of those presently used in current marketed implantable cardiac pacemakers.

Microcomputer circuit 302 controls the operational functions of digital controller/timer 330, specifying which

timing intervals are employed, and controlling the duration of the various timing intervals, via data and control bus 306. Microcomputer circuit 302 contains a microprocessor 304 and associated system clock 308 and on processor RAM circuits 310 and 312, respectively. In addition, microcomputer circuit 302 includes a separate RAM/ROM chip 314. Microprocessor 304 is interrupt driven, operating in a reduced power consumption mode normally, and awakened in response to defined interrupt events, which may include delivery of atrial and ventricular pacing pulses as well as sensed atrial and ventricular depolarizations. In addition, if the device operates as a rate responsive pacemaker, a timed interrupt, e.g., every cycle or every two seconds, may be provided in order to allow the microprocessor to analyze the sensor data and update the basic rate interval (A-A or V-V) of the device. In addition, in a preferred embodiment of the invention, the microprocessor 304 may also serve to define variable A-V escape intervals and atrial and ventricular refractory periods which may also decrease in duration along with decreases in duration of the basic rate interval. Specifically, the microprocessor is used to carry out the routines illustrated in Figures 4A, 4B and 6A-6C.

The illustrated circuitry of Figure 3 is merely exemplary, and corresponds to the general functional organization of most microprocessor controlled cardiac pacemakers presently commercially available. It is believed that the present invention is most readily practiced in the context of such a device, and that the present invention can therefore readily be practiced using the basic hardware of existing microprocessor controlled dual chamber pacemakers, as presently available, with the invention implemented primarily by means of modifications to the software stored in the ROM 312 of the microprocessor circuit 302. However, the present invention many also be usefully practiced by means of a full custom integrated circuit, or any combination of hardware and software.

Referring now to Figure 4A, there is shown a generalized flow diagram of steps taken by a pacemaker system in accordance with this invention in performing synchronous pacing, with adjustment of AV_{esc} for optimal HOCM therapy. The steps of this flow diagram are suitably carried out by microcomputer circuit 302. This is a simplified flow diagram setting forth only steps pertinent to controlling AV_{esc}, and does not include many other steps and responses that occur during each cycle of a typical dual chamber pacemaker. The illustrated logic of Figure 4A recognizes that the intrinsic AV conduction time following an atrial pace pulse is greater than following a sensed atrial depolarization, by an amount described as "atrial sense offset", or ASO. The AV_{esc} following an atrial pace is defined as PAV; the AV_{esc} following an atrial pace is defined as PAV; the AV_{esc} following an atrial sense is defined as SAV; and PAV = SAV + ASO .

At block 401, the routine of Fig. 4A is waiting for what is expected to be an atrial event. When an event occurs, the routine goes to block 402 and determines whether there has been timeout of the atrial escape interval, A_{esc}. If yes, this indicates that an atrial pace (AP) should be delivered, and this is done at block 404. Following this, the routine sets AV_{esc} to PAV, and initiates timeout of AV_{esc}. Returning to 402, if there has been no timeout of A_{esc}, the pacemaker proceeds to 408, and determines whether there has been an early ventricular sense (VS). If yes, the routine branches to block 409 and resets the timing appropriately, whereafter it returns to block 401. However, as would normally be the case, if at 408 the event is not a VS, meaning that it has been an atrial sense (AS), the routine proceeds to block 410 and sets AV_{esc} to the current value of SAV. Following this, the routine goes to 412 and initiates timeout of the atrial escape interval (A_{esc}), and timeout of the AV escape interval, AV_{esc} (either SAV or PAV). Then, at 414, the pacer waits for the next event, normally a ventricular event.

At 415, the pacemaker responds to an event by first determining whether the event was a timeout of AV_{esc}. If no, meaning that there was a ventricular sense, the pacemaker proceeds to block 417 and resets PAV and SAV to a shorter value which ensures capture by the next ventricular pace pulse. For example, each of these values can be decremented by 20 or 50 ms, to ensure that succeeding timeouts of AV_{esc} occur early enough for complete capture. It is to be noted, however, that the algorithms discussed below are designed to avoid an occurrence of VS, such that the pacemaker should rarely take this path.

If at 415 there has been a timeout of V_{esc}, then the pacemaker proceeds to block 418 and delivers a V pace. Then, at block 419, the pacemaker determines whether it is programmed to go into the AV adjust routine. If no, the routine is done and it exits back to 401. If yes, the pacemaker goes to the adjust AV routine at block 420. Here, the pacemaker analyzes collected data, e.g., VP-FFRS time; FFRS duration; or FFRS or QRS amplitude. With this data in hand, the pacemaker system can adjust the values of PAV and SAV, in accordance with a predetermined algorithm for changing AV_{esc} so as to optimize resultant pre-excitation. Following this, the routine returns to block 401 and waits for the next atrial event.

Note that the pacemaker can be programmed for automatically monitoring AV data and adjusting AV_{esc} each pacemaker cycle, or these steps can be taken on some other periodic or user-programmed basis, within the scope of the invention. For an implanted pacemaker which is set to automatically adjust AV, the pacemaker goes directly to 420. Similarly, for a pacemaker system in accordance with this invention which is adapted to be programmed specifically by a physician, the routine exits unless the programming sequence has been activated.

Figure 4B is a simple flow diagram of the primary

steps of an adjust AV routine that includes a "search", or scan, whereby AV_{esc} is varied in accord with a predetermined program. At block 426, the pacemaker system monitors the data from which an indication of AV optimization is derived, e.g. FFRS duration or VP-FFRS time. Following this, at 427, the monitored data is analyzed and a decision is made as to whether the AV delay requires adjustment based upon the monitored data. Specific embodiments of this determination are set forth in Figs. 6A-6C. The routine then branches to 428 and adjusts the value or values of AV delay. However, if no adjustment is indicated, the routine proceeds to 429 and determines whether AV search is to be undertaken. If no, the routine exits, but if yes the routine goes to block 430 and carries out a search whereby typically the AV escape interval is incremented cyclically or every n cycles toward a value corresponding to the patient's intrinsic conduction. For example, AV_{esc} can be incremented 5 ms every cycle, or every n cycles, until either fusion is detected, or there is a ventricular sense. Figure 6A gives a specific example of a search.

Referring now to Figure 5A, there is shown a plot of data representative of QRS or FFRS duration (ms) as a function of pacemaker AV escape interval (ms). It is to be noted that a particularly reliable measure of QRS duration can be obtained from the FFRS signal in and around the "fusion" range between full capture by the pacing pulse, and ventricular sense. As is seen in Figure 5A, the QRS duration is relatively low at higher AV intervals which are greater than the patient's intrinsic PR conduction time, i.e., where a VS occurs before timeout of AV_{esc}. However, as AV_{esc} is shortened, it comes into a fusion area where QRS increases up to a knee value (illustrated at about 150 ms); at shorter intervals, where a VP results in full capture, QRS duration is substantially constant. The portion between full capture and failure to capture is termed the fusion area, or range, and the ability to detect duration changes in this area, as seen from FFRS signals, provides the basis for one embodiment of this invention. Although Figure 5A illustrates QRS data, the FFRS data corresponds directly, and in particular is characterized by the same knee, or breakpoint, between the fusion range and the lower full capture range. The knee is seen to be at the onset of fusion.

Referring now to Figure 5B, there is shown a plot of the time between a delivered ventricular pacing pulse (VP) and the sensed FFRS, i.e., Dt = VP - FFRS. The VP-FFRS duration is measured from the time of delivery of the ventricular pacing pulse to the time when the leading edge of the FFRS is detected to rise to a predetermined threshold amplitude. The variation of VP-QRS follows the same form, i.e., the duration is longest corresponding to short AV intervals when the delivered pacing pulse captures the heart, and drops during the fusion range. What is important is that the Δt/AV curve exhibits the same knee characteristic as seen in the QRS/AV curve of Fig. 5A. As used herein, the phrase "VP-FFRS knee" refers to the point on the VP-FFRS vs. AV interval curve where VP-FFRS starts to drop from its maximum value toward lower values at higher AV intervals.

Referring now to Fig. 6A, there is shown a flow diagram of more detailed steps for carrying out a search routine to obtain data from which an adjusted SAV is determined. At 515, the pacemaker system determines whether the ventricular event has been a V sense. If no, meaning that a ventricular pace pulse was delivered, the routine goes to block 535 and determines whether a search flag has been set. If no, meaning that no search is currently in operation, the routine goes to block 536 and determines whether to initiate a search. A search may be triggered either by an external program signal, or by a signal generated automatically by the pacemaker, e.g. after a predetermined number of cycles or a predetermined amount of time. If no search is indicated, the routine exits. However, if a search is indicated, at 529 the pacemaker first decrements the AV delay by a small increment $\Delta 2$, to provide that the search starts at an AV delay which is safely short of the fusion area. Following this, at 537 the search flag is set.

Returning to 535, if it is found that the search flag is set, the routine goes to block 540 takes initial steps for obtaining data. For an embodiment which uses VP-FFRS time, the pacer starts a clock to time out the time from the delivered ventricular pace pulse to the detected FFRS. The pacemaker also generates a sense window connected through control 350 for a predetermined duration adjusted to exclude the T-wave, e.g. up to 300 ms. The sense window acts on the atrial sense amplifier, and the FFRS is channeled through line 352 to circuit 330, where it is detected as shown at flow block 542. Following this, at block 544, the pacemaker system gets and stores the value of the applicable parameter, e.g., VP-FFRS time (T_{NX}). Thus, the time is obtained from the clock which had been set at 540, and the variable T_{NX} is stored. In the embodiment where the width of the FFRS signal is utilized, this width is obtained from the FFRS signal and stored. In the embodiment where the amplitude of the FFRS is utilized, the amplitude is obtained and the variable A_{NX} is stored.

The steps 542, 544 of sensing and processing the FFRS signal are accomplished by standard hardware, preferably also using digital processing techniques. For getting the time of VP-FFRS, a standard edge detector may be utilized in circuit 330 to sense when the leading edge of the FFRS signal has reached a predetermined level, or has increased by a predetermined percentage. For determining width, or duration, the signal is processed to determine when it first rises to a predetermined level, and when it falls back below such level. And amplitude is measured by either a simple peak detector, or other standard amplitude detection circuitry. These standard circuits may be supplemented or replaced by known digital processing techniques, carried out with

the aid of microprocessor system 302.

Following the operations at 544, the routine goes to 545 and determines whether the variable X has reached a maximum. This variable corresponds to the number of cycles that data has been taken at the same AV value. If X has not yet reached X_{max}, e.g. 5, the routine increments X at 546. If X does equal X_{max}, the routine sets X equal to 0 at block 548, and at block 560 increments the value of AV_N, setting $AV_N = AV_{N-1} + \Delta 3$, where $\Delta 3$ is a predetermined increment, e.g. 2 or 5 ms. At 561, N is incremented by 1, for purposes of accurate storage at block 544. In this manner, X measurements can be taken at N representative search values of AV_{esc}.

Returning to step 515, if a V sense is detected, AV is immediately decremented at 528, e.g., by $\Delta 2 = 20$ ms, to prevent further cycles without pacing capture. At 552, the system determines whether the search flag has been set. If no, this means that there has been a V sense without a search, and the routine exits. If yes, this means that AV has been lengthened to the point where capture is lost. The search flag is reset at 554, and the variable N is set equal to 0 at 555. Then, at 560, the system initiates the Find SAV routine, as described more fully in the embodiments of Figures 6B and 6C. Initiation of the Find SAV routine may be done automatically within the pacemaker, or the data can be downloaded to the programmer for analysis and determination of an optimum value of SAV.

Referring now to Figure 6B, there is shown a first embodiment of the Find SAV routine 560 for obtaining an adjusted SAV as a function of FFRS width (duration). At 601, the average width value (W_N) corresponding to the X values of each AV_N during the search is determined. This may be done by any suitable processing technique, preferably obtaining a sample rolling average. Following this step for each value of N, resulting in M values of average width, the variable N is set equal to 1 at 602. At 604 the pacemaker compares the difference of W_N-W_{N+1} against a predetermined increment Δ. This step thus determines whether the QRS width (W_{N+1}), as represented by the measured FFRS width, is significantly shorter than the value at the next shorter AV interval (W_N). To allow for jitter and timing vagaries, the algorithm preferably is set to determine a substantial change in width as being only greater than Δ, e.g. 15 ms. If such a differential is not found, the routine goes to 605 and determines whether N has stepped through the maximum number of values for which data is available, i.e., N = M. If no, at 607 N is incremented by 1 and the routine returns to step 604. At the point where the differential between adjacent AV values exceeds Δ, the routine branches to block 608 and determines a new SAV to be equal to the just prior value of AV, i.e. SAV (N - 1). Following this, the determined value of SAV is displayed at 610. Alternatively, for an implanted pacemaker, the new value of SAV can be automatically adopted.

Referring back to the illustrative plot of Figure 5A, for this data the algorithm of Fig. 6B proceeds to the point where it determines that the AV interval of about 160 ms is the first to have an averaged width which falls outside the allowed range, i.e., the differential of AV_{N+1} to AV_N is greater than Δ. The algorithm then assumes that the AV interval of about 150 ms, AV(N), is an optimum point, and subtracts one AV interval increment to obtain AV (N-1), at approximately 140 ms. By this means, an AV value at or just less than the knee is determined.

Referring now to Fig. 6C, there is shown a flow diagram that corresponds to Figure 6B, but which determines the optimum value of SAV in terms of T_N, the time between the ventricular pace pulse and the evoked response as detected through the FFRS (VP-FFRS). At block 620, the average of T_N is obtained from the X measured values corresponding to each value of N. This produces an array of values of T_N corresponding to the M different values of AV_N utilized during the search routine. Following this, at 622 the variable N is set equal to 1. At 624, T_N is compared to T_{N+1}, to see if the difference is greater than a predetermined increment Δ. Note that as AV interval increases, the system is looking for the knee corresponding to a decrease in T_N. When this decrease first exceeds the predetermined increment, this indicates the onset of fusion, and the routine branches to block 628 and sets SAV equal to SAV(N-1). The premise in this subroutine is the same as for Figure 6B, i.e., the first AV interval which corresponds to a substantial decrease in time is just down the slope from the knee. Accordingly, selecting the just prior value of AV, corresponding to T_{N+1}, represents a factor of safety. It is seen that if no interval difference as computed at 624 exceeds the predetermined increment, the routine loops continuously until N = M, at which time the information is displayed. The physician can inspect this data and choose from it an optimum value of SAV.

There has thus been disclosed a pacemaker system for dual chamber synchronous pacing optimized for cardiomyopathy therapy, and particularly for HOCM therapy. In a preferred embodiment of this invention, the pacemaker system detects the FFRS and processes the signal to determine at least one characteristic thereof. The system collects data representative of a selected FFRS characteristic or several characteristics, over a range of values of AV escape interval, which values include the fusion range or zone. The FFRS characteristic is suitably VP-FFRS time; FFRS duration; or FFRS amplitude; or any combination of these variables. Thus, the parameter for determining AV may be X, where X = fn (amplitude) + fn (duration) + fn (timing). In another embodiment of the system of this invention, the R-wave may be monitored directly and a characteristic derived from it, e.g. amplitude or VP-QRS time, in which case the system utilizes these characteristics in the same manner to determine the optimum adjustment of AV escape interval.

The novel technique of using the FFRS to determine optimal AV_{esc} has been illustrated with the pre-

ferred embodiment of scanning, or searching to determine the "knee" also sometimes called the bending point of the VP-FFRS curve, from which a new value of AV_{esc} is determined. However, the pacemaker of this invention further includes monitoring an FFRS characteristic, e.g., VP-FFRS time, or VP-QRS time, to determine when operation may be in the fusion range. Thus, referring back to Fig. 4B, the monitored data can simply be inspected each cycle to see whether there has been a decrease in the interval, i.e., whether a shortening of the VP-FFRS duration indicates the onset of fusion. In this case, even though no search as such has been conducted in order to determine the knee, the pacemaker of this invention senses the onset of fusion and adjusts AV_{esc} by shortening it. The scope of the invention thus embraces ongoing cyclical monitoring of an FFRS characteristic, as well as searching to acquire batch data from which an accurate determination of the knee is obtained.

It is further noted that the system as claimed can utilize a number of different configurations. Thus, an implantable pacemaker used in this invention can contain hardware and/or software for control of AV_{esc} upon command from an external programmer; upon command from a "patient activator"; automatically, based on internal logic, e.g., elapsed time or number of pacemaker cycles; or based on some other parameter or criteria being met, e.g., change in one or more sensor levels. Also, the practice of the invention embraces the use of an external pacemaker and the like, and available technology for transmitting data to and from the patient location.

Claims

1. A dual chamber pacemaker system, having atrial sense means for sensing signals from a patient's atrium, ventricular sense means for sensing ventricular signals from a patient, ventricular pace means for generating and delivering ventricular pacing pulses to said patient's right ventricle, AV_{esc} means for setting and timing an AV escape interval from the occurrence of a sensed atrial signal, and sync control means for controlling delivery of ventricular pacing pulses at the time out of said AV escape interval in the absence of a sensed ventricular signal, characterized by FFRS, QRS or ventricular septal pre-excitation sense means for detecting FFRSs, QRSs or ventricular septal pre-excitation following delivered ventricular pacing pulses, further comprising analyzing means for analyzing said detected FFRSs, QRSs or ventricular septal pre-excitation and determining from variations in said detected FFRSs, QRSs or ventricular septal pre-excitation an optimised value of said AV escape interval, said AV_{esc} means having adjusting means for adjusting said AV escape interval in accordance with said optimised value.

2. The pacemaker system as described in claim 1, comprising timing means for timing the respective time intervals between delivered ventricular pacing pulses and the timing of following detected FFRSs, QRSs or ventricular septal pre-excitation and wherein said analyzing means has determining means for determining said optimised value from said time intervals.

3. The pacemaker system as described in claim 1, wherein said analyzing means has means for determining the AV_{esc} interval which approximately corresponds to the knee-point of said time interval sequence of detected FFRSs, QRSs or ventricular septal pre-excitations, said knee-point being a point on relevant parameter versus AV curves occurring at the onset of fusion.

4. The pacemaker system as described in claim 1, 2 or 3 comprising duration means for determining the durations of detected FFRSs, or QRSs and wherein said analyzing means has means for determining said optimised value from said durations.

5. The pacemaker system as described in claim 1, 2, 3 or 4 wherein said AV_{esc} means comprises AV search means for periodically increasing said AV escape interval from a value at which a ventricular pace pulse achieves complete capture toward a value at which a ventricular pace pulse fails to achieve complete capture.

6. The pacemaker system as described in claim 5, wherein said analyzing means has timing means for determining a VP-FFRS or VP-QRS or pre-excitation knee which corresponds to a particular value in the series of AV escape intervals so searched.

7. The pacemaker system as described in claim 6, wherein said adjusting means comprises means for shortening said AV escape interval to a value less than the AV escape interval corresponding to said knee.

8. The pacemaker system as described in any preceding claim, comprising search means for varying said AV escape interval through respective values thereof in accord with a predetermined search pattern, and wherein said analyzing means comprises data means for collecting FFRS, QRS or ventricular septal pre-excitation data representative of at least one predetermined FFRS, QRS or ventricular septal pre-excitation characteristic corresponding to each value of AV escape interval within said search.

9. The pacemaker system as described in claim 8, wherein said analyzing means further comprises

fusion means for analyzing said collected data to determine a value of AV escape interval corresponding to the breakpoint between full capture pacing and fusion.

10. The pacemaker system as described in claim 8, comprising programmer means for programming initiation of said search means to carry out said search pattern.

11. The pacemaker system as described in claim 8, comprising external programmer means having said analyzing means, and telemetry means for telemetering said data to said external programmer means.

12. The pacemaker system as described in claim 8, wherein said predetermined FFRS, QRS or ventricular septal pre-excitation characteristic is FFRS, QRS or ventricular septal pre-excitation duration, and comprising means for comparing the FFRS, QRS or ventricular septal pre-excitation duration value at a given AV escape interval to the FFRS, QRS or ventricular septal pre-excitation duration value corresponding to the next shorter value of AV escape interval, and for determining the shortest value of AV escape interval at which said comparison produces a difference greater than a predetermined factor.

13. The pacemaker system as described in claim 1, wherein said analyzing means comprises means for determining the longest AV escape interval corresponding to the occurrence some degree of fusion and for providing an indication of an AV escape interval just shorter than said corresponding interval.

14. The pacemaker system as described in claim 1, further comprising atrial pacing means for delivering atrial pacing pulses, and wherein said AV_{esc} means sets and times an AV escape interval from the occurrence of a delivered atrial pacing pulse.

15. A dual chamber pacemaker system as set forth in claim 1, further characterized by having:

AV varying means for varying said AV escape interval in accord with a predetermined search pattern,
measure means for detecting a measure of QRS waves evoked by a delivered ventricular pulse at said varied AV escape intervals,
programmable batch data means for collecting data representative of respective QRS measure signals and corresponding values of AV escape interval,
programmable analyzing means for analyzing said collected data to determine a value of AV escape interval corresponding to the onset of fusion, and
said AV escape means having adjusting means for adjusting said AV escape interval as a function of said determined value of AV escape interval corresponding to the onset of fusion.

16. The pacemaker system as described in claim 15, wherein said batch data means comprises means for collecting data representative of the duration of evoked QRS signals at respective escape intervals.

17. The pacemaker system as described in claim 16, comprising FFRS means for detecting FFRS signals from the sensed signals from the patient's atrium, and wherein said analyzing means has means for analyzing said FFRS signals to determine a measure of QRS duration.

18. The pacemaker system as described in claim 15, wherein said batch data means comprises means for collecting data representative of the amplitude of evoked QRS waves.

19. The pacemaker system as described in claim 18, comprising FFRS means for detecting FFRS signals from said sensed signals from the patient's atrium, and wherein said analyzing means comprises means for analyzing said FFRS signals to determine a measure of QRS duration.

20. The pacemaker system as described in claim 15, wherein said batch data means comprises means for collecting data representative of the time intervals between delivered ventricular pace pulses and resulting evoked QRS signals corresponding to a plurality of values of AV escape interval.

21. The pacemaker system as described in claim 20, wherein said batch data means comprises means for detecting FFRS signals, and wherein said analyzing means comprises means for determining time intervals from delivered ventricular pacing pulses to said FFRS signals.

22. The pacemaker system as described in claim 15, wherein said system further comprises an external programmer means for activating said batch data means and said analyzing means.

23. The pacemaker system as described in claim 22, further comprising external ECG leads for providing the signals to said atrial sense means and said ventricular sense means.

24. The pacemaker system as described in claim 22, further providing telemetry means for transferring

said collected data to said programmer.

25. A dual chamber pacemaker system, as set forth in claim 1, wherein the time duration between a delivered ventricular pacing pulse and a following evoked QRS are measured by a timing means and a correspondence determined between a varied AV escape interval varied according to a predetermined variation pattern and said time duration, and further comprising:

    analyzing means for analyzing the said time duration measures to determine a value of AV escape interval corresponding to the onset of fusion.

26. The pacemaker system as described in claim 25, wherein said timing means is operative continuously each pacemaker cycle having a delivered ventricular pacing pulse, and said adjust means adjusts the value of AV escape interval upon a determination of onset of fusion.

27. The pacemaker system as described in claim 25, comprising programmer means for enabling said timing means and said analyzing means.

28. The pacemaker system as described in claim 27, comprising ECG leads connected from said patient to said atrial sense means and said ventricular sense means.

29. The pacemaker system as described in claim 27, comprising telemetry means for transmitting data representative of said measures of time duration to said programmer.

Patentansprüche

1. Zweikammer-Schrittmachersystem mit einer atriellen Wahrnehmeinrichtung zum Wahrnehmen von Signalen aus dem Atrium eines Patienten, einer ventrikulären Wahrnehmeinrichtung zum Wahrnehmen von ventrikulären Signalen des Patienten, einer ventrikulären Stimuliereinrichtung zur Erzeugung und Abgabe von ventrikulären Stimulierimpulsen an den rechten Ventrikel des Patienten, einer AV_{esc}-Einrichtung zur Vorgabe und Zeitsteuerung eines AV-Escapeintervalls ab dem Auftreten eines wahrgenommenen atriellen Signals, und einer Synchron-Steuereinrichtung zum Steuern der Abgabe von ventrikulären Stimulierimpulsen bei Ablauf des AV-Escapeintervalls und fehlender Wahrnehmung eines ventrikulären Signals, **gekennzeichnet** durch eine FFRS-, QRS- oder Ventrikulärseptal-Vorerregungs-Wahrnehmeinrichtung zum Erfassen von FFRS- oder QRS-Ereignissen oder Ventrikulärseptal-Vorerregungen im Anschluß an abgegebene ventrikuläre Stimulierimpulse, sowie ferner eine Analysiereinrichtung zum Analysieren der erfaßten FFRS- oder QRS-Ereignisse oder Ventrikulärseptal-Vorerregungen und zum Bestimmen eines optimierten Wertes für das AV-Escapeintervall aus Schwankungen in den erfaßten FFRS- oder QRS-Ereignissen oder Ventrikulärseptal-Vorerregungen, wobei die AV_{esc}-Einrichtung eine Einstelleinrichtung zum Einstellen des AV-Escapeintervalls entsprechend dem optimierten Wert aufweist.

2. Schrittmachersystem nach Anspruch 1 mit einer Zeitsteuereinrichtung zur Zeitsteuerung der jeweiligen Zeitintervalle zwischen abgegebenen ventrikulären Stimulierimpulsen und dem Zeitpunkt nachfolgender erfaßter FFRS- oder QRS-Ereignisse oder Ventrikulärseptal-Vorerregungen, wobei die Analysiereinrichtung eine Bestimmungseinrichtung zum Bestimmen des optimierten Wertes aus den Zeitintervallen aufweist.

3. Schrittmachersystem nach Anspruch 1, wobei die Analysiereinrichtung eine Einrichtung zum Bestimmen des AV_{esc}-Intervalls aufweist, das im wesentlichen dem Kniepunkt der Zeitintervallfolge von erfaßten FFRS- oder QRS-Ereignissen oder Ventrikulärseptal-Vorerregungen entspricht, wobei der Kniepunkt ein beim Einsetzen von Fusionen auftretender Punkt auf Kurven ist, in denen ein relevanter Parameter über der AV-Zeit aufgetragen ist.

4. Schrittmachersystem nach Anspruch 1, 2 oder 3 mit einer Zeitdauereinrichtung zum Bestimmen der Zeitdauer erfaßter FFRS- oder QRS-Ereignisse, wobei die Analysiereinrichtung eine Einrichtung zum Bestimmen des optimierten Wertes aus den Zeitdauern aufweist.

5. Schrittmachersystem nach einem der Ansprüche 1 bis 4, wobei die AV_{esc}-Einrichtung eine AV-Sucheinrichtung aufweist, die das AV-Escapeintervall von einem Wert, bei dem ein ventrikulärer Stimulierimpuls eine vollständige Mitnahme bewirkt, periodisch in Richtung eines Wertes erhöht, bei dem ein ventrikulärer Stimulierimpuls keine vollständige Mitnahme mehr bewirkt.

6. Schrittmachersystem nach Anspruch 5, wobei die Analysiereinrichtung eine Zeitsteuereinrichtung aufweist, um in einem VP-FFRS- oder VP-QRS-Ereignis oder eine Vorerregung ein Knie zu bestimmen, das einem bestimmten Wert in der Folge von auf diese Weise gesuchten AV-Escapeintervallen entspricht.

7. Schrittmachersystem nach Anspruch 6, wobei die Einstelleinrichtung eine Einrichtung zum Verkürzen des AV-Escapeintervalls auf einen Wert aufweist,

der unter dem dem Knie entsprechenden AV-Escapeintervall liegt.

8. Schrittmachersystem nach einem der vorhergehenden Ansprüche mit einer Sucheinrichtung zum Variieren des AV-Escapeintervalls über dessen jeweilige Werte entsprechend einem vorbestimmten Suchmuster, wobei die Analysiereinrichtung eine Dateneinrichtung zum Sammeln von FFRS-, QRS- oder VentrikularseptalVorerregungs-Date aufweist, die mindestens eine dem jeweiligen Wert des AV-Escapeintervalls innerhalb der Suche entsprechende Eigenschaft eines FFRS- oder QRS-Ereignisses oder einer Ventrikulärseptal-Vorerregung angibt.

9. Schrittmachersystem nach Anspruch 8, wobei die Analysiereinrichtung ferner eine Fusionseinrichtung aufweist, um die gesammelten Daten zur Bestimmung eines Wertes des AV-Escapeintervalls analysiert, der der Bruchstelle zwischen Stimulation mit voller Mitnahme und Fusion entspricht.

10. Schrittmachersystem nach Anspruch 8 mit einer Programmiereinrichtung zum Programmieren der Sucheinrichtung derart, daß sie mit der Durchführung des Suchmusters beginnt.

11. Schrittmachersystem nach Anspruch 8 mit einer die Analysiereinrichtung aufweisenden externen Programmiereinrichtung und einer Telemetrieeinrichtung zur telemetrischen Übertragung der Daten an die externe Programmiereinrichtung.

12. Schrittmachersystem nach Anspruch 8, wobei die vorgegebene Eigenschaft des FFRS- oder QRS-Ereignisses oder der Ventrikulärseptal-Vorerregung dessen bzw. deren Dauer ist, mit einer Einrichtung, die den Wert dieser Dauer bei einem gegebenen AV-Escapeintervall mit dem Wert der Dauer entsprechend dem nächstkürzeren Wert des AV-Escapeintervalls vergleicht und den kürzesten Wert des AV-Escapeintervalls bestimmt, bei dem der Vergleich eine über einem vorgegebenen Faktor liegende Differenz liefert.

13. Schrittmachersystem nach Anspruch 1, wobei die Analysiereinrichtung eine Einrichtung zum Bestimmen des längsten AV-Escapeintervalls, das dem Auftreten eines bestimmten Fusionsgrades entspricht, und zur Erzeugung einer Anzeige eines AV-Escapeintervalls aufweist, das gerade unter dem besagten entsprechenden Intervall liegt.

14. Schrittmachersystem nach Anspruch 1 mit einer atriellen Stimuliereinrichtung zur Abgabe atrieller Stimulierimpulse, wobei die AV_{esc}-Einrichtung ein AV-Escapeintervall ab dem Auftreten eines abgegebenen atriellen Stimulierimpulses vorgibt und zeitlich steuert.

15. Zweikammerschrittmacher nach Anspruch 1, ferner gekennzeichnet durch:

    eine AV-Variiereinrichtung zum Variieren des AV-Escapeintervalls entsprechend einem vorgegebenen Suchmuster,
    eine Meßeinrichtung zum Erfassen eines Maßes von QRS-Komplexen, die bei den variierten AV-Escapeintervallen von einem abgegebenen Ventrikülarimpuls hervorgerufen werden,
    eine programmierbare Stapeldateneinrichtung zum Sammeln von Daten, die jeweils QRS-Meßsignale und entsprechende Werte des AV-Escapeintervalls angeben, und
    eine programmierbare Analysiereinrichtung zum Analysieren der gesammelten Daten, um einen dem Einsetzen von Fusionen entsprechenden Wert des AV-Escapeintervalls zu bestimmen,
    wobei die AV-Escapeeinrichtung eine Einstelleinrichtung zum Einstellen des AV-Escapeintervalls als Funktion des dem Einsetzen von Fusionen entsprechenden bestimmten Wertes des AV-Escapeintervalls aufweist.

16. Schrittmachersystem nach Anspruch 15, wobei die Stapeldateneinrichtung eine Einrichtung zum Sammeln von Daten aufweist, die die Dauer von bei jeweiligen Escapeintervallen hervorgerufenen QRS-Signalen angeben.

17. Schrittmachersystem nach Anspruch 16 mit einer FFRS-Einrichtung zum Erfassen von FFRS-Signalen aus den im Atrium des Patienten wahrgenommenen Signalen, wobei die Analysiereinrichtung eine Einrichtung zum Analysieren der FFRS-Signale zum Bestimmen eines Maßes der QRS-Dauer aufweist.

18. Schrittmachersystem nach Anspruch 15, wobei die Stapeldateneinrichtung eine Einrichtung zum Sammeln von Daten aufweist, die die Amplitude der hervorgerufenen QRS-Komplexen angeben.

19. Schrittmachersystem nach Anspruch 18 mit einer FFRS-Einrichtung zum Erfassen von FFRS-Signalen aus den im Atrium des Patienten wahrgenommenen Signalen, wobei die Analysiereinrichtung eine Einrichtung zum Analysieren der FFRS-Signale zum Bestimmen eines Maßes der QRS-Dauer aufweist.

20. Schrittmachersystem nach Anspruch 15, wobei die Stapeldateneinrichtung eine Einrichtung zum Sam-

meln von Daten aufweist, die die Zeitintervalle zwischen abgegebenen ventrikulären Stimulierimpulsen und den daraus resultierenden hervorgerufenen QRS-Signalen entsprechend mehreren Werten des AV-Escapeintervalls angeben.

21. Schrittmachersystem nach Anspruch 20, wobei die Stapeldateneinrichtung eine Einrichtung zum Erfassen von FFRS-Signalen aufweist und die Analysiereinrichtung eine Einrichtung zum Bestimmen von Zeitintervallen von abgegebenen ventrikulären Stimulierimpulsen an bis zu den FFRS-Signalen enthält.

22. Schrittmachersystem nach Anspruch 15, wobei das System ferner eine externe Programmiereinrichtung zum Aktivieren der Stapeldaten- und der Analysiereinrichtung aufweist.

23. Schrittmachersystem nach Anspruch 22 mit externen EKG-Leitungen zum Zuführen der Signale an die atrielle und die ventrikuläre Wahrnehmeinrichtung.

24. Schrittmachersystem nach Anspruch 22 mit einer Telemetrieeinrichtung zur Übertragung der gesammelten Daten an die Programmiereinrichtung.

25. Zweikammer-Schrittmachersystem nach Anspruch 1, wobei die Zeitdauer zwischen einem abgegebenen ventrikulären Stimulierimpuls und einem anschließenden, hervorgerufenen QRS-Ereignis von einer Zeitsteuereinrichtung gemessen und eine Übereinstimmung zwischen einem entsprechend einem vorgegebenen Variationsmuster variierten AV-Escapeintervall und der Zeitdauer bestimmt wird, mit ferner

    einer Analysiereinrichtung zum Analysieren der gemessenen Zeitdauern, um einen dem Einsetzen von Fusionen entsprechenden Wert des AV-Escapeintervalls zu bestimmen.

26. Schrittmachersystem nach Anspruch 25, wobei die Zeitsteuereinrichtung in jedem einen abgegebenen ventrikulären Stimulierimpuls enthaltenden Schrittmacherzyklus kontinuierlich arbeitsfähig ist und die Einstelleinrichtung den Wert des AV-Escapeintervalls nach einer Bestimmung des Einsetzens von Fusionen einstellt.

27. Schrittmachersystem nach Anspruch 25 mit einer Programmiereinrichtung zur AnSteuerung der Zeitsteuer- und der Analysiereimichtung.

28. Schrittmachersystem nach Anspruch 27 mit den Patient mit der atriellen und der ventrikulären Wahrnehmeinrichtung verbindenden EKG-Leitungen.

29. Schrittmachersystem nach Anspruch 27 mit einer Telemetrieeinrichtung zum Übertragen von die Zeitdauer-Meßwerte angebenden Daten an die Programmiereinrichtung.

Revendications

1. Système de stimulation cardiaque à deux chambres, comportant des moyens de détection auriculaire pour détecter des signaux provenant d'une oreillette d'un patient, des moyens de détection ventriculaire pour détecter des signaux ventriculaires provenant d'un patient, des moyens de stimulation ventriculaire pour produire et délivrer des impulsions de stimulation ventriculaire audit ventricule droit du patient, des moyens de réglage de AV_{esc} pour le réglage et le cadencement d'un intervalle auriculoventriculaire AV d'échappement à partir de l'apparition d'un signal auriculaire détecté, et des moyens de commande de synchronisation pour commander la délivrance d'impulsions de stimulation ventriculaire du dépassement de temps dudit intervalle AV d'échappement en l'absence d'un signal ventriculaire détecté, caractérisé par des moyens de détection d'un signal FFRS, d'un signal QRS ou d'une pré-excitation septale ventriculaire pour la détection de signaux FFRS, de signaux QRS ou d'une pré-excitation septale ventriculaire à la suite d'impulsions de stimulation ventriculaire délivrées, comportant en outre des moyens d'analyse pour analyser lesdits signaux FFRS détectés, lesdits signaux QRS détectés ou ladite pré-excitation septale ventriculaire détectée et déterminer, à partir de variations desdits signaux FFRS détectés, desdits signaux QRS détectés ou de ladite pré-excitation septale ventriculaire détectée, une valeur optimisée dudit intervalle AV d'échappement, lesdits moyens de réglage de AV_{esc} comportant des moyens d'ajustement pour ajuster ledit intervalle AV d'échappement en fonction de ladite valeur optimisée.

2. Système de stimulateur cardiaque selon la revendication 1, comprenant des moyens de cadencement pour commander de façon cadencée les intervalles de temps respectifs entre des impulsions de stimulation ventriculaire délivrées et commander de façon cadencée les signaux FFRS détectés suivants, les signaux QRS détectés suivants ou la pré-excitation septale ventriculaire détectée suivante, et dans lequel lesdits moyens d'analyse comportent des moyens de détermination pour déterminer ladite valeur optimisée à partir desdits intervalles de temps.

3. Système de stimulateur cardiaque selon la revendi-

cation 1, dans lequel lesdits moyens d'analyse possèdent des moyens pour déterminer l'intervalle AV_{esc} qui correspond approximativement au coude de ladite séquence d'intervalles de temps des signaux FFRS détectés, des signaux QRS détectés ou des pré-excitations septales ventriculaires détectées, ledit coude étant un point sur les courbes de variation du paramètre concerné en fonction de AV, apparaissant au début de la fusion.

4. Système de stimulateur cardiaque selon la revendication 1, 2 ou 3, comprenant des moyens de détermination de durées pour déterminer les durées de signaux FFRS détectés ou de signaux QRS détectés, et dans lequel lesdits moyens d'analyse comportent des moyens pour déterminer ladite valeur optimisée à partir desdites durées.

5. Système de stimulateur cardiaque selon la revendication 1, 2, 3 ou 4, dans lequel lesdits moyens de réglage de AV_{esc} comprennent des moyens d'examen de AV servant à augmenter périodiquement ledit intervalle AV d'échappement depuis une valeur, pour laquelle une impulsion de stimulation ventriculaire atteint une capture complète vers une valeur pour laquelle l'impulsion de stimulation ventriculaire ne permet pas d'obtenir la synchronisation complète.

6. Système de stimulateur cardiaque selon la revendication 5, dans lequel lesdits moyens d'analyse possèdent des moyens de cadencement pour déterminer un coude de VP-FFRS ou de VP-QRS ou de pré-excitation qui correspond à une valeur particulière dans la série d'intervalles d'échappement AV ainsi examinés.

7. Système de stimulateur cardiaque selon la revendication 6, dans lequel lesdits moyens d'ajustement comprennent des moyens pour réduire l'intervalle AV d'échappement à une valeur inférieure à l'intervalle AV d'échappement correspondant audit coude.

8. Système de stimulateur cardiaque tel que décrit dans l'une quelconque des revendications précédentes, comprenant des moyens d'examen pour modifier ledit intervalle AV d'échappement en parcourant des valeurs respectives de cet intervalle conformément à une configuration d'examen prédéterminée, et dans lequel lesdits moyens d'analyse comprennent des moyens de données pour collecter des données de FFRS, des données de QRS ou des données de pré-excitation septale ventriculaire, représentatives d'au moins une caractéristique FFRS, une caractéristique QRS ou une caractéristique de pré-excitation septale ventriculaire, prédéterminée, correspondant à chaque valeur de l'intervalle AV d'échappement au cours dudit examen.

9. Système de stimulateur cardiaque selon la revendication 8, dans lequel lesdits moyens d'analyse comprennent en outre des moyens de détermination de la fusion pour l'analyse desdites données collectées pour déterminer une valeur de l'intervalle AV d'échappement correspondant au point d'interruption entre la stimulation à capture complète et la fusion.

10. Système de stimulateur cardiaque selon la revendication 8, comprenant des moyens formant programmateur pour programmer le déclenchement desdits moyens d'examen pour l'exécution dudit profil d'examen.

11. Système de stimulateur cardiaque selon la revendication 8, comprenant des moyens formant programmateur externe comportant lesdits moyens d'analyse, lesdits moyens de télémétrie pour la transmission télémétrique desdites données auxdits moyens formant programmateur externe.

12. Système de stimulateur cardiaque selon la revendication 8, dans lequel ladite caractéristique prédéterminée du signal FFRS, du signal QRS ou de la pré-excitation septale ventriculaire est la durée du signal FFRS, du signal QRS ou de la pré-excitation septale ventriculaire, et comprenant des moyens pour comparer la valeur de la durée du signal FFRS, du signal QRS ou de la pré-excitation septale ventriculaire, pour un intervalle AV d'échappement donné à la valeur de durée du signal FFRS, du signal QRS ou de la pré-excitation septale ventriculaire correspondant à la valeur plus courte suivante de l'intervalle AV d'échappement, et pour déterminer la valeur la plus courte de l'intervalle AV d'échappement, pour laquelle ladite comparaison produit une différence supérieure à un facteur prédéterminé.

13. Système de stimulateur cardiaque selon la revendication 1, dans lequel lesdits moyens d'analyse comprennent des moyens pour déterminer l'intervalle AV d'échappement le plus long qui correspond à l'apparition d'un certain degré de fusion ou pour fournir une indication d'un intervalle AV d'échappement juste un peu plus court que ledit intervalle correspondant.

14. Système de stimulateur cardiaque selon la revendication 1, comprenant en outre des moyens de stimulation auriculaire servant à délivrer des impulsions de stimulation auriculaire, et dans lequel lesdits moyens de réglage de AV_{esc} règlent et commandent de façon cadencée un intervalle d'échap-

pement à partir de l'apparition d'une impulsion de stimulation auriculaire délivrée.

15. Système de stimulateur à deux chambres tel qu'indiqué dans la revendication 1, caractérisé en outre en ce qu'il comporte :

des moyens de modification de AV servant à modifier ledit intervalle AV d'échappement conformément à un profil de recherche prédéterminé;
des moyens de mesure pour détecter une mesure d'ondes QRS déclenchées par une impulsion ventriculaire délivrée, formant lesdits intervalles d'échappement AV modifiés,
des moyens programmables de collecte de données de lots pour collecter des données représentatives de signaux respectifs de mesure du signal QRS et de valeurs correspondantes d'un intervalle AV d'échappement,
des moyens d'analyse programmables pour analyser lesdites données collectées pour déterminer une valeur de l'intervalle AV d'échappement correspondant au début de la fusion, et
lesdits moyens d'échappement AV comportant des moyens d'ajustement servant à ajuster ledit intervalle AV d'échappement en fonction de ladite valeur déterminée de l'intervalle d'échappement correspondant au début de la fusion.

16. Système de stimulateur cardiaque selon la revendication 15, dans lequel lesdits moyens de collecte de données de lots comprennent des moyens pour collecter des données représentatives de la durée de signaux QRS déclenchés, pendant des intervalles d'échappement respectifs.

17. Système de stimulateur cardiaque selon la revendication 16, comprenant des moyens de détection de signaux FFRS servant à détecter des signaux FFRS à partir des signaux détectés à partir de l'oreillette du patient, et dans lequel lesdits moyens d'analyse comportent des moyens pour analyser lesdits signaux FFRS pour déterminer une mesure de la durée des signaux QRS.

18. Système de stimulateur selon la revendication 15, dans lequel des moyens de données de lots comprennent des moyens pour collecter des données représentatives de l'amplitude des ondes QRS déclenchées.

19. Système de stimulateur selon la revendication 18, comprenant des moyens de détection de signaux FFRS pour détecter des signaux FFRS à partir desdits signaux détectés provenant de l'oreillette du patient, et dans lequel lesdits moyens d'analyse comprennent des moyens pour analyser lesdits signaux FFRS pour déterminer une mesure de la durée du signal QRS.

20. Système de stimulateur selon la revendication 15, dans lequel lesdits moyens de collecte de données de lots comprennent des moyens pour collecter des données représentatives des intervalles de temps entre des impulsions de stimulation ventriculaire délivrées et des signaux QRS déclenchés résultants correspondant à une pluralité de valeurs de l'intervalle AV d'échappement.

21. Système de stimulateur selon la revendication 20, dans lequel lesdits moyens de collecte de données de lots comprennent des moyens pour détecter des signaux FFRS, et dans lequel lesdits moyens d'analyse comprennent des moyens pour déterminer des intervalles de temps à partir d'impulsions de stimulation ventriculaire délivrées auxdits signaux FFRS.

22. Système de stimulateur selon la revendication 15, dans lequel ledit système comprend en outre des moyens formant programmateur externe pour activer lesdits moyens de collecte de données de lots et lesdits moyens d'analyse.

23. Système de stimulateur selon la revendication 22, comprenant en outre des conducteurs des fils extérieurs de transmission d'électrocardiogrammes pour envoyer des signaux auxdits moyens de détection auriculaire et auxdits moyens de détection ventriculaire.

24. Système de stimulateur selon la revendication 22, comprenant en outre des moyens de télémétrie pour transférer lesdites données collectées audit programmateur.

25. Système de stimulateur selon la revendication 1, dans lequel l'intervalle de temps entre une impulsion de stimulation ventriculaire délivrée et un signal QRS déclenché suivant est mesuré par des moyens de cadencement, et une correspondance déterminée entre un intervalle AV d'échappement modifié conformément à un profil de variation prédéterminé, est modifiée en fonction d'un profil de variation prédéterminé et dudit intervalle de temps, et comprenant en outre :

des moyens d'analyse pour analyser lesdites mesures d'intervalles de temps pour déterminer la valeur d'un intervalle AV d'échappement correspondant au début de la fusion.

26. Système de stimulateur selon la revendication 25,

dans lequel lesdits moyens de cadencement peuvent agir continûment sur chaque cycle du stimulateur ayant une impulsion de stimulation ventriculaire délivrée, et lesdits moyens d'ajustement ajustent la valeur de l'intervalle AV d'échappement lors d'une détermination du début de fusion.

27. Système de stimulateur selon la revendication 25, comprenant des moyens formant programmateur servant à valider lesdits moyens de cadencement et lesdits moyens d'analyse.

28. Système de stimulateur selon la revendication 27, comprenant des fils de transmission d'électrocardiogrammes connectés entre ledit patient et lesdits moyens de détection auriculaire et lesdits moyens de détection ventriculaire.

29. Système de stimulateur selon la revendication 27, comprenant des moyens de télémétrie pour transmettre des données représentatives desdites mesures d'intervalle de temps audit programmateur.

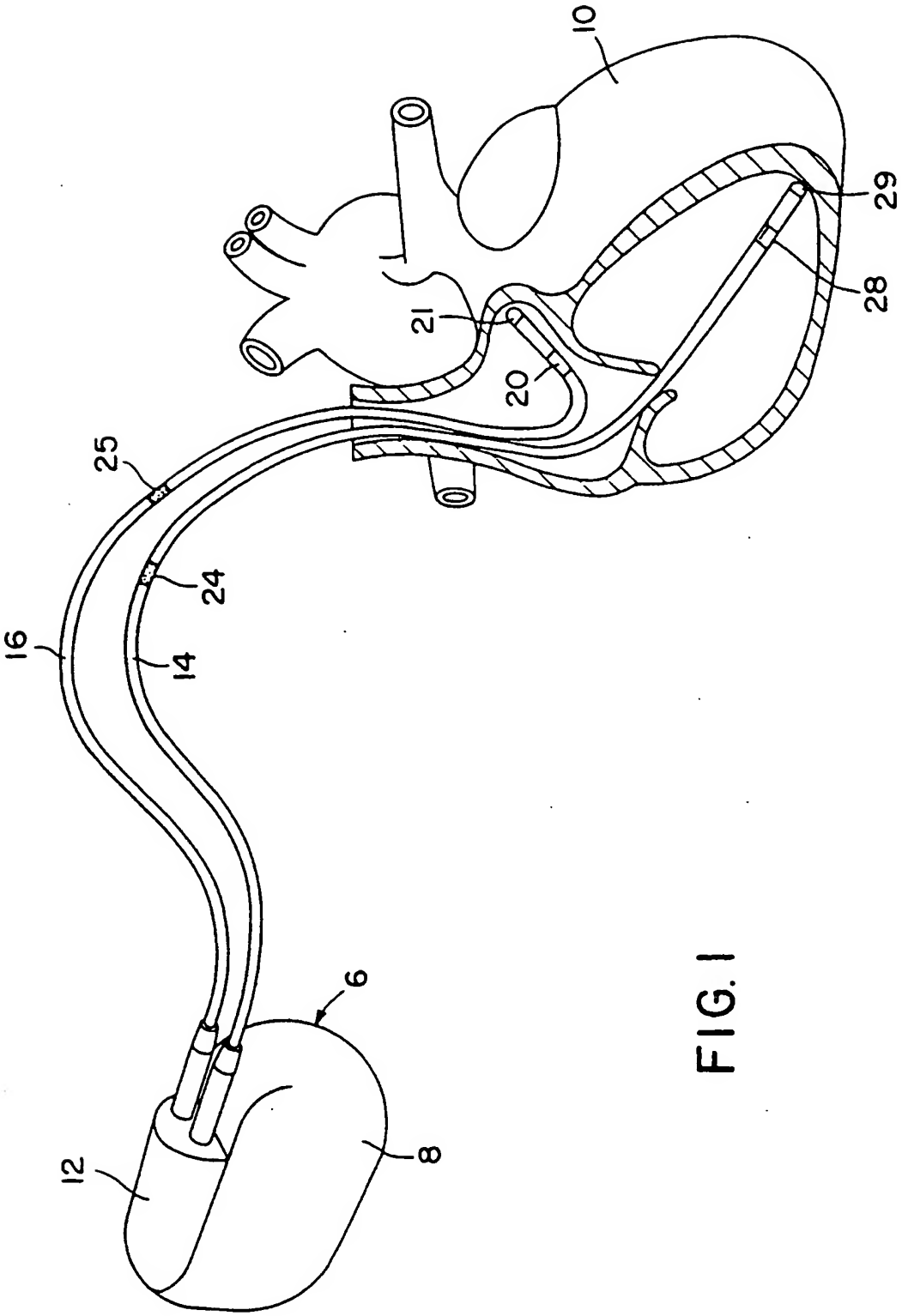

FIG. 1

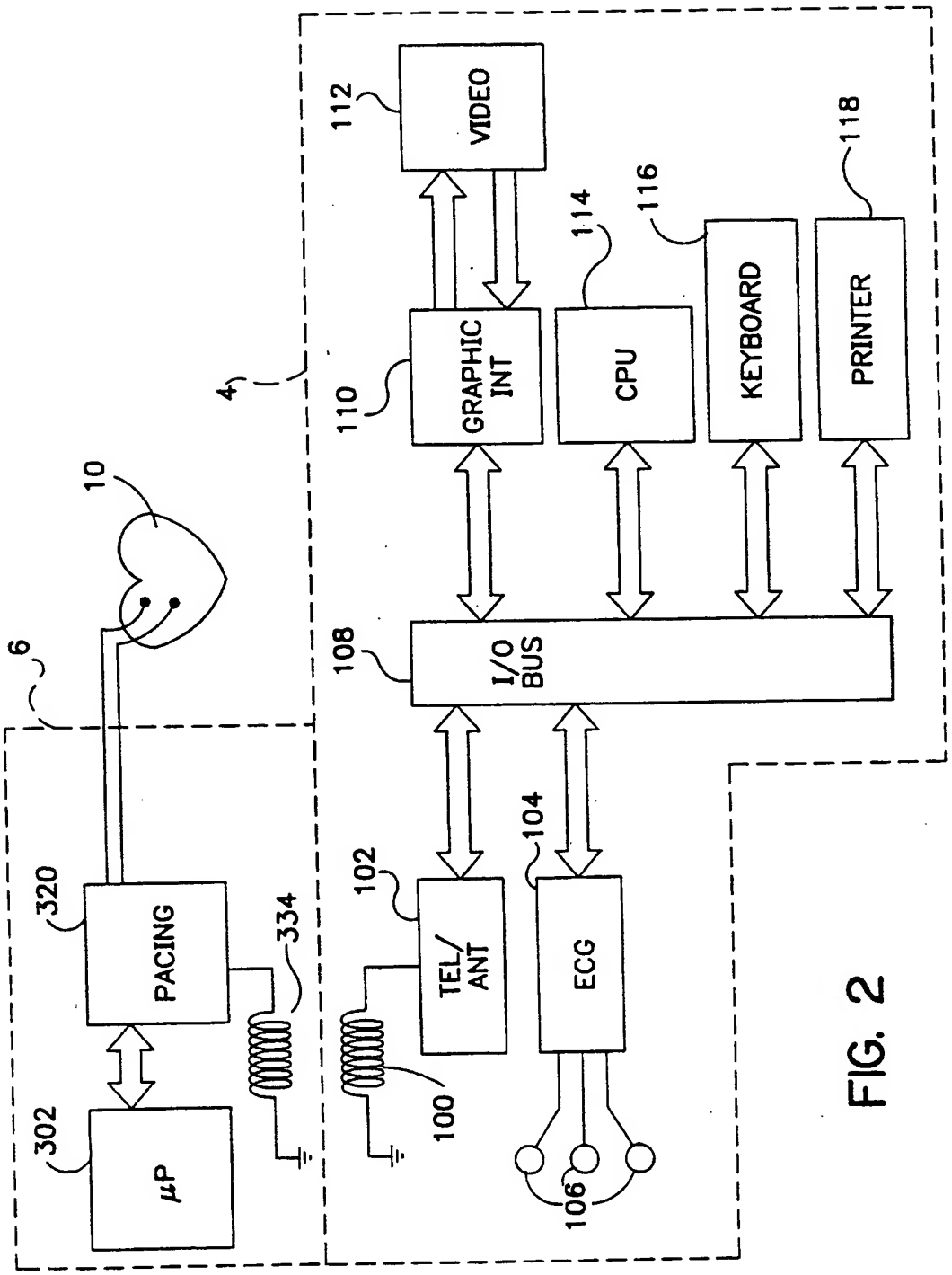
4
6
10
112
VIDEO
110
GRAPHIC INT
114
CPU
116
KEYBOARD
118
PRINTER
108
I/O BUS
102
TEL/ ANT
104
ECG
320
PACING
334
302
μP
100
106

FIG. 2

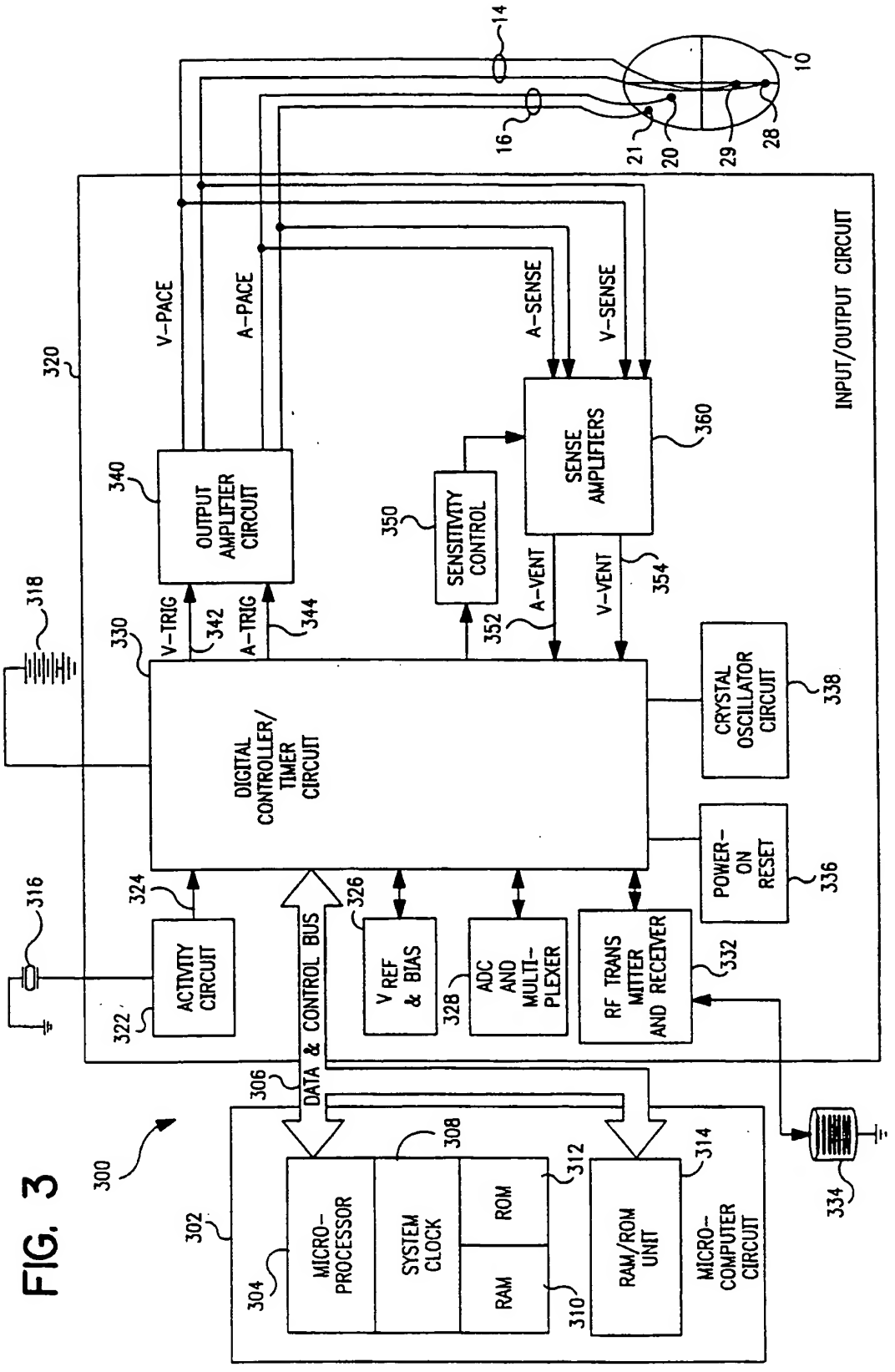
14
10
16
21
20
29
28
INPUT/OUTPUT CIRCUIT
320
V-PACE
A-PACE
A-SENSE
V-SENSE
340
OUTPUT AMPLIFIER CIRCUIT
350
SENSITIVITY CONTROL
SENSE AMPLIFIERS
360
318
330
V-TRIG
342
A-TRIG
344
352
A-VENT
V-VENT
354
DIGITAL CONTROLLER/ TIMER CIRCUIT
CRYSTAL OSCILLATOR CIRCUIT
338
POWER-ON RESET
336
316
324
326
ACTIVITY CIRCUIT
322
DATA & CONTROL BUS
V REF & BIAS
328
ADC AND MULTI-PLEXER
RF TRANS MITTER AND RECEIVER
332
306
300
308
312
314
334
302
MICRO-PROCESSOR
SYSTEM CLOCK
ROM
RAM
RAM/ROM UNIT
MICRO-COMPUTER CIRCUIT
304
310

FIG. 3

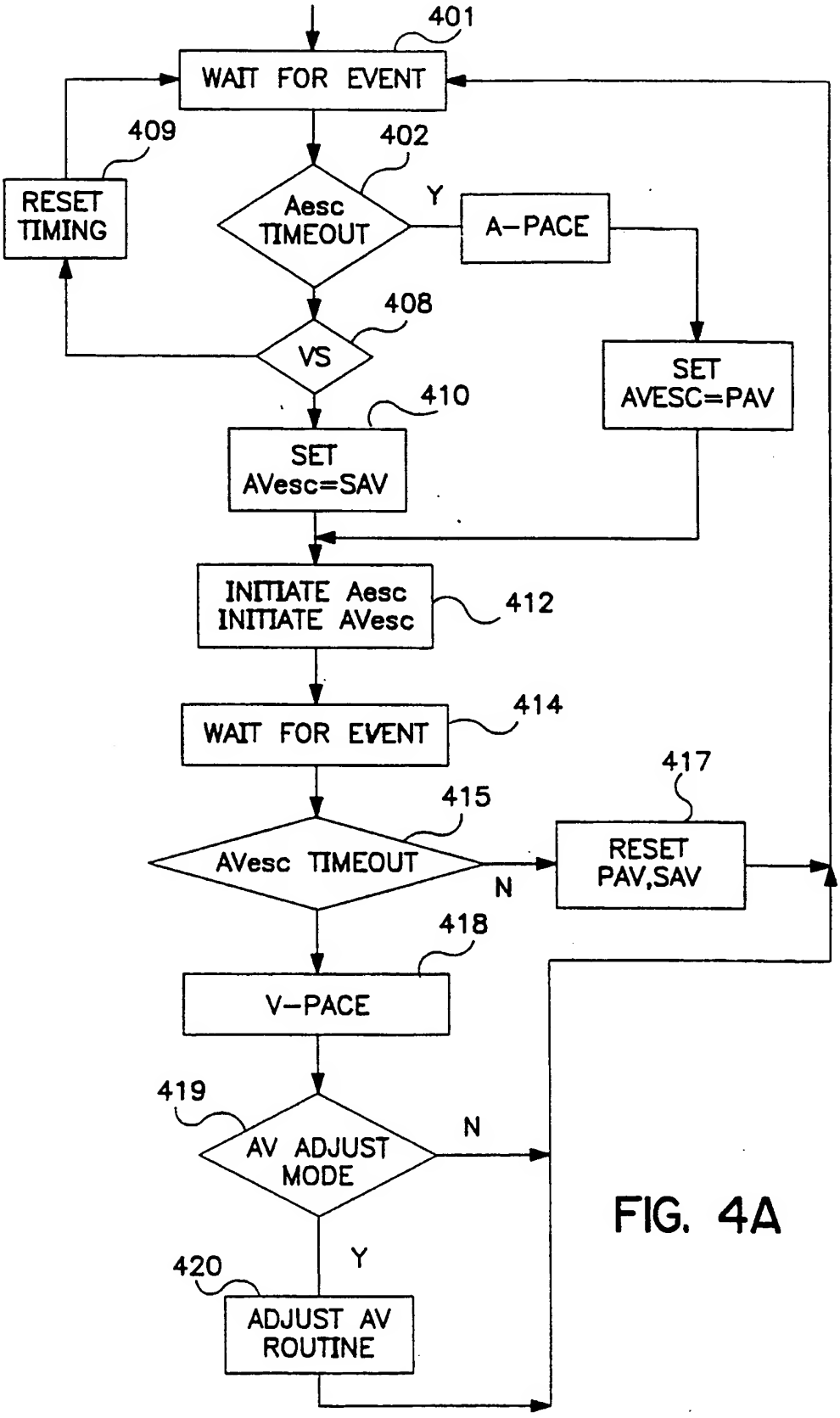
401
WAIT FOR EVENT
409
RESET TIMING
402
Aesc TIMEOUT
Y
A-PACE
408
VS
SET AVESC=PAV
410
SET AVesc=SAV
INITIATE Aesc
INITIATE AVesc
412
WAIT FOR EVENT
414
417
415
AVesc TIMEOUT
N
RESET PAV,SAV
418
V-PACE
419
AV ADJUST MODE
N
Y
420
ADJUST AV ROUTINE

FIG. 4A

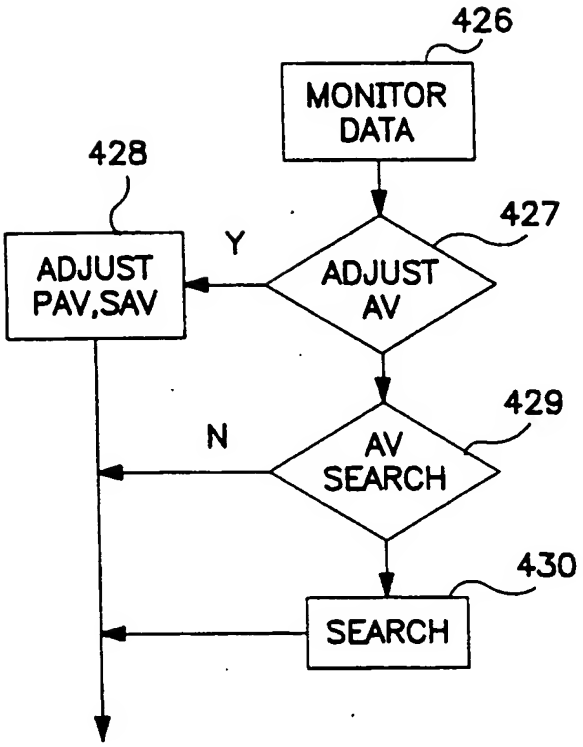
426
MONITOR DATA
427
ADJUST AV
Y
428
ADJUST PAV,SAV
429
AV SEARCH
N
430
SEARCH

FIG. 4B

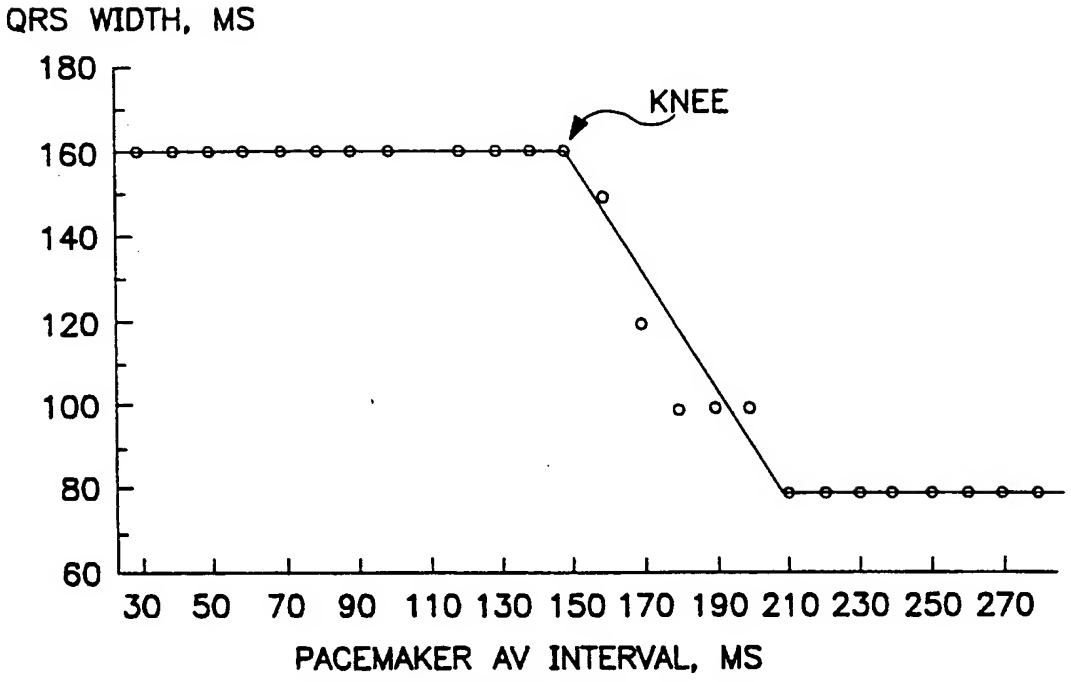
QRS WIDTH, MS
180
160
140
120
100
80
60
KNEE
30 50 70 90 110 130 150 170 190 210 230 250 270
PACEMAKER AV INTERVAL, MS

FIG. 5a

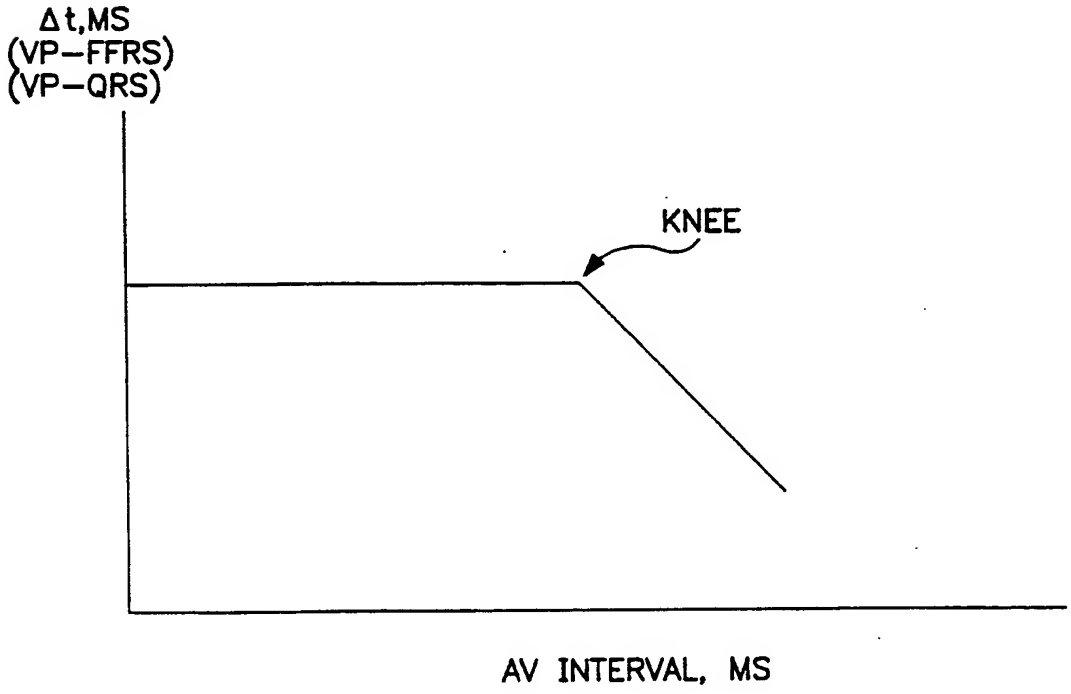
Δt,MS
(VP−FFRS)
(VP−QRS)
KNEE
AV INTERVAL, MS

FIG. 5b

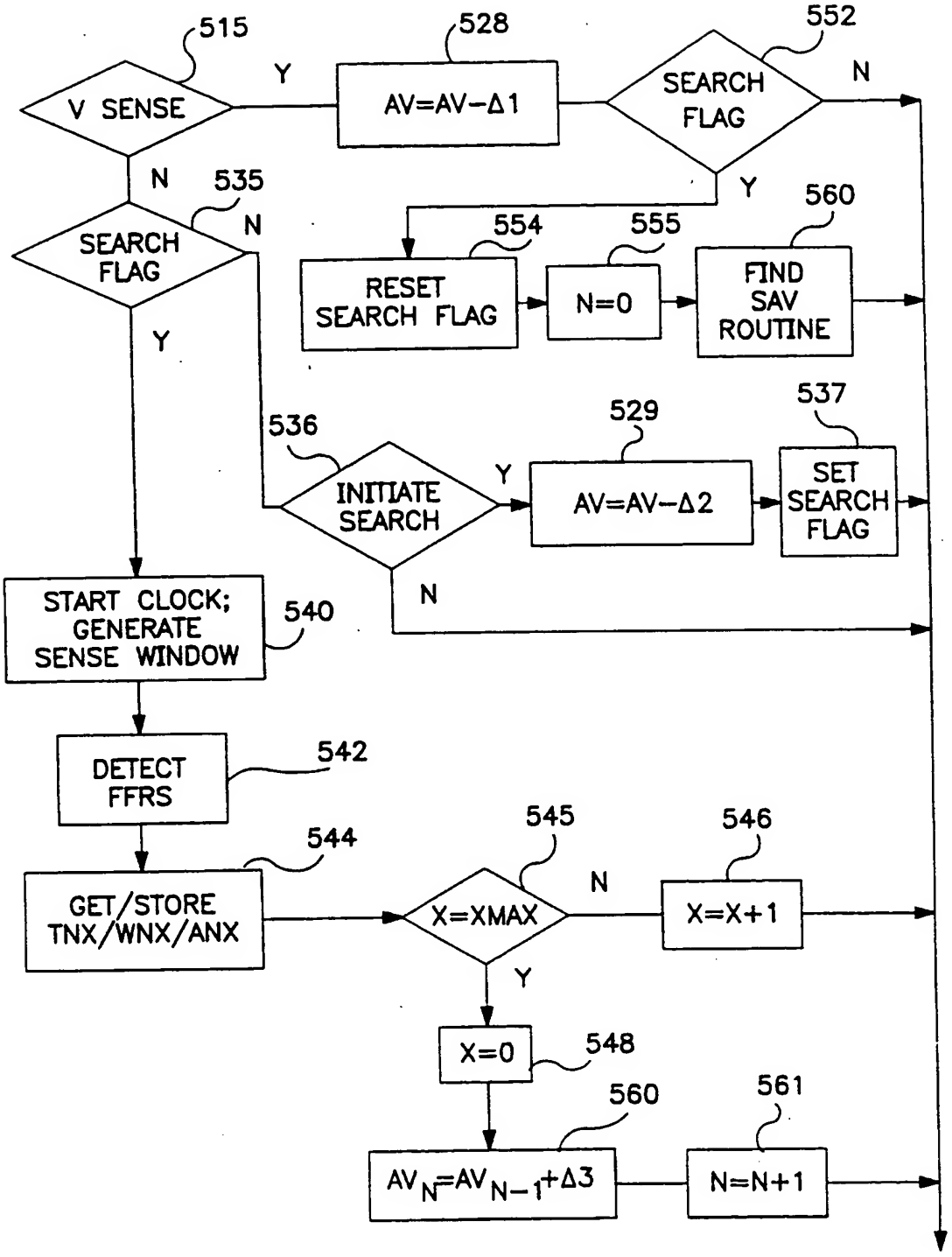
515
V SENSE
Y
528
AV=AV−Δ1
552
SEARCH FLAG
N
Y
N
535
SEARCH FLAG
N
Y
554
RESET SEARCH FLAG
555
N=0
560
FIND SAV ROUTINE
536
INITIATE SEARCH
Y
529
AV=AV−Δ2
537
SET SEARCH FLAG
N
START CLOCK; GENERATE SENSE WINDOW
540
DETECT FFRS
542
GET/STORE TNX/WNX/ANX
544
545
X=XMAX
N
546
X=X+1
Y
X=0
548
560
AV N=AV N−1+Δ3
561
N=N+1

FIG. 6A

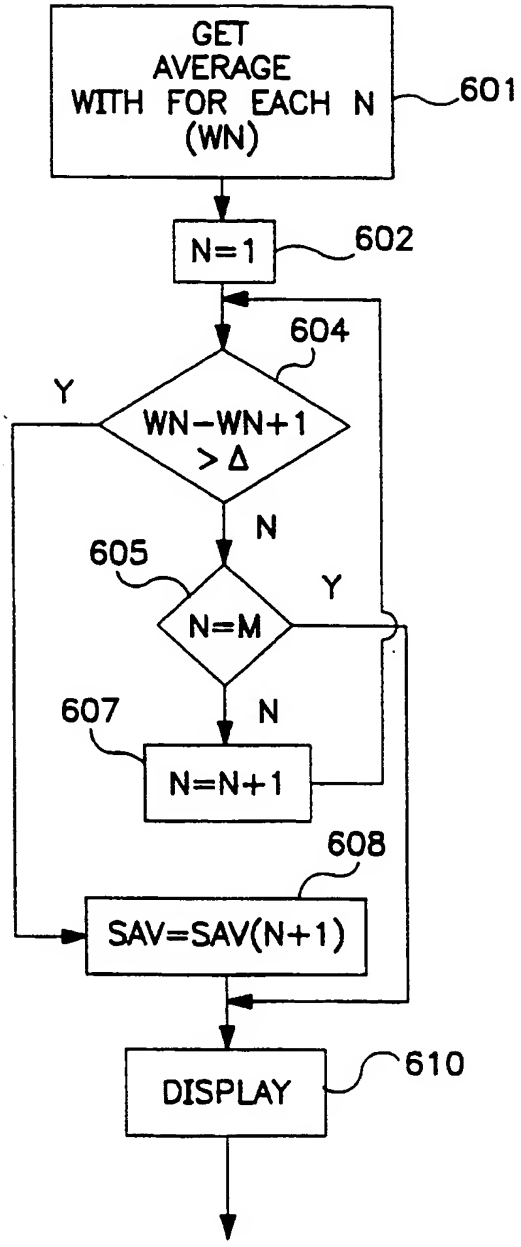
GET AVERAGE WITH FOR EACH N (WN)
601
N=1
602
604
WN−WN+1 > Δ
Y
N
605
N=M
Y
607
N
N=N+1
608
SAV=SAV(N+1)
DISPLAY
610

FIG. 6B

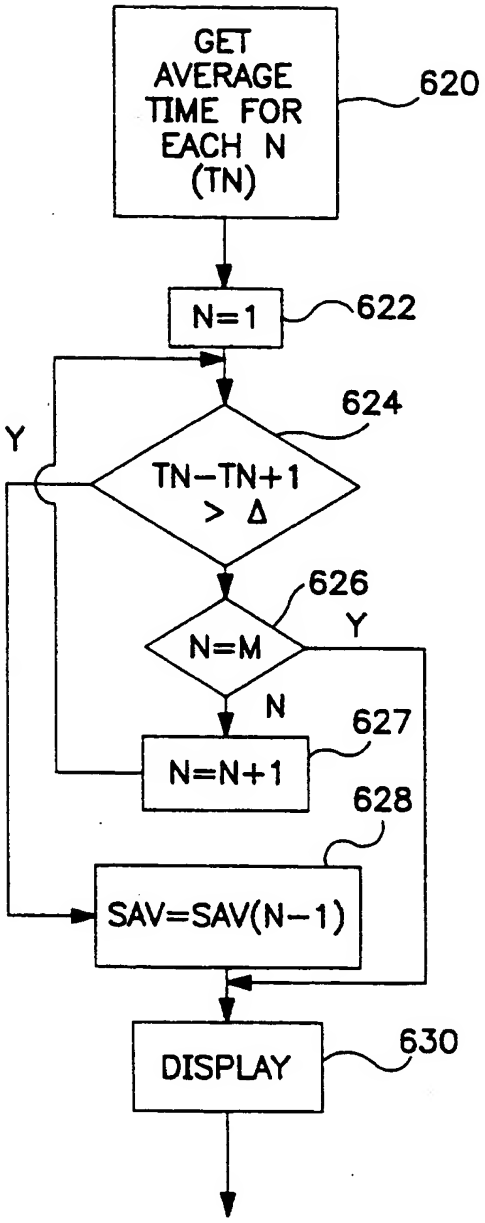
GET AVERAGE TIME FOR EACH N (TN)
620
N=1
622
624
TN−TN+1 > Δ
Y
626
N=M
Y
N
627
N=N+1
628
SAV=SAV(N−1)
DISPLAY
630

FIG. 6C